

UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: James L. Yeager, Nadir Büyüktimkin and Servet Büyüktimkin

Application No.: 10/656,906 Filed Date: September 5, 2004

Confirmation No. 9093 Group: 1623 Examiner: Unassigned

For: Methods of Treatment of Male Erectile Dysfunction

CERTIFICATE OF MAILING	
I Hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450	
on <u>2/20/04</u>	<u>Mary Anza</u>
Date	Signature
<u>Mary Anza</u>	
Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(More than 3 months after receipt of the International Search Report, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Enclosed herewith is form PTO-1449:

- ☒ Copies of the cited references other than U.S. Patents and Published Applications are enclosed.
- ☐ In accordance with 37 C.F.R. § 1.98 (d), copies of cited references (*list reference not enclosed*) are not enclosed as these references were entered in earlier application, U.S. Application No. [], to which the present application claims priority under 35 U.S.C. 120. The earlier application contains copies of the cited references.
- ☐ If copies of references [*list references not enclosed*] would benefit the Examiner of this case, the Examiner is invited to call the undersigned attorney and copies will be forwarded immediately.
- ☒ Listed references AP2, AQ2, AZ5, AR6, AS6, AT6, AU6, and AV6 were cited in the enclosed International Search Report in a counterpart foreign application.

Concise Explanation Requirement (non-English references):

- ☒ The "concise explanation" requirement (non-English references) for reference AT3 under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☒ the enclosed English language abstract.

☐ Applicant requests that the following pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. [], Publication No. [], Publication Date [],
by [inventor(s)], filed [], Docket No.: []

____ U.S. Patent Application No. [], Publication No. [], Publication Date [],
by [inventor(s)], filed [], Docket No.: []

____ U.S. Patent Application No. [], Publication No. [], Publication Date [],
by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account No. 50-1935 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account No. 50-1935.

Respectfully submitted,

BOWDITCH & DEWEY, LLP

By 

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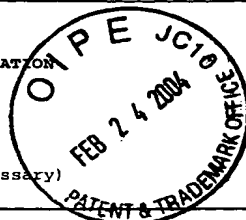
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PTO-1449 REPRODUCED

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

February 18, 2004

(Use several sheets if necessary)

ATTORNEY DOCKET NO.
301888.3002-120APPLICATION NO.
10/656,906APPLICANT
James L. Yeager, *et al.*FILING DATE
September 5, 2003GROUP ART UNIT
1623

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	2,818,855	Jan 7 1958	Miller, <i>et al.</i>			
	AB	4,127,118	Nov 28 1978	Latorre			
	AC	4,254,145	Mar 3 1981	Birnbaum			
	AD	4,311,707	Jan 19 1982	Birnbaum, <i>et al.</i>			
	AE	4,801,587	Jan 31 1989	Voss, <i>et al.</i>			
	AF	4,980,378	Dec 25 1990	Wong, <i>et al.</i>			
	AG	5,242,391	Sep 7 1993	Place, <i>et al.</i>			
	AH	5,256,652	Oct 26 1993	El-Rashidy			
	AI	5,380,760	Jan 10, 1995	Wendel, <i>et al.</i>			
	AJ	5,820,587	Oct 13, 1998	Place			
	AK	5,843,961	Dec 1 1998	Kock, <i>et al.</i>			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL	WO 91/16021	31 OCT 91	PCT			
	AM	WO 99/65303	23 DEC 99	PCT			
	AN	WO 00/33825	15 JUN 00	PCT			
	AO	WO 00/69469	23 NOV 00	PCT			
	AP	0 357 581	07 MAR 90	EPO			
	AQ	1 367 550	18 SEP 74	GB			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	AR	Droller, M.J. <i>et al.</i> , "Impotence. Consensus Development Conference Statement, National institutes of Health," <i>JAMA</i> , 270(1): 83-90 (1993).
	AS	Murray, F.T. <i>et al.</i> , "Evaluation and Treatment of Erectile Dysfunction, <i>Amer. J. Medical Sci.</i> , 309: 99-109 (1995).
	AT	O'Keefe, M. <i>et al.</i> , Assessment and Treatment of Impotence," <i>Medical Clinics of North America</i> , 79: 415-434 (1995).
	AU	Vickers, M.A. <i>et al.</i> , "Diagnosis and Treatment of Psychogenic Erectile Dysfunction in a Urological Setting: Outcomes of 18 Consecutive Patients," <i>J. Urology</i> , 149: 1258-1261 (1993).

EXAMINER

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U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA2	6,102,849	Aug 15 2000	Hakac			
	AB2	6,046,244	Apr 2000	Büyüktimkin <i>et al.</i> ,	514	785	
	AC2	5,942,545	Aug 24 1999	Samour <i>et al.</i>	514	573	
	AD2	6,451,807	Sep 17, 2002	Emmick, et al.	514	287	
	AE2	6,113,939	Sep. 5, 2000	Place, et al.	424	430	
	AF2	6,244,573	May 1, 2001	Yeager, et al.	604	181	
	AG2	6,118,020	Sep 12, 2000	Büyüktimkin, et al.	560	155	
	AH2	6,418,934	Jul 16, 2002	Chin	128	898	
	AI2	6,323,241	Nov 27, 2001	Yeager, et al.	514	573	
	AJ2	6,007,824	Dec 28, 1999	Duckett, et al.	424	195.1	
	AK2	4,861,764	Aug 29, 1989	Samour, et al.	514	177	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL2	0 552 405	28 JUL 93	EPO			
	AM2	WO 99/22714	14 MAY 99	PCT			
	AN2	WO 01/35998	25 MAY 01	PCT			
	AO2	WO 01/74279	11 OCT 01	PCT			
	AP2	WO 03 070281 A1	28 AUG 03	PCT			
	AQ2	WO 01/51053 A1	19 JULY 01	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	AV	Padma-Nathan, H., <i>et al.</i> , "Treatment of Men with Erectile Dysfunction with Transurethral Alprostadil," <i>N. Eng. J. Med.</i> , 336: 1-7 (1997) (see especially Fig. 1).
	AW	Peterson, C.A., <i>et al.</i> , "Erectile Response to Transurethral Alprostadil, Prazosin and Aprostadil-Prazosin Combinations," <i>J. Urol.</i> , 159: 1523-1528 (1998).
	AX	Porst, H., "Transurethral Alprostadil with MUSE™ (Medicated Urethral System for Erection) vs. Intracavernous Alprostadil-a Comparative Study in 103 Patients with Erectile Dysfunction," <i>Int. J. Impot. Res.</i> , 9: 187-192 (1997).
	AY	Benson, G., (see editorial comment), <i>J. Urol.</i> , 159: 1527-1528 (1998).

EXAMINER	DATE CONSIDERED
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EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA3	5,082,866	Jan 21, 1992	Wong, et al.	514	785	
	AB3	6,007,824	Dec 28, 1999	Duckett, et al.	424	195.1	
	AC3	4,771,004	Sept 13, 1988	Higuchi	436	5	
	AD3						
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FOREIGN PATENT DOCUMENTS							
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	AL3						
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AZ	Büyüktimkin, <i>et al.</i> , "Chemical Means of Transdermal Drug Permeation Enhancement" in <i>Transdermal and Topical Drug Delivery Systems</i> , Ghosh T.K., Pfister W.R., Yum S.I. (Eds.), Interpharm Press Inc., Buffalo Groves, IL. (1997).					
	AR2	Pudney J., and Anderson, D.J., "Immunobiology of the Human Penile Urethra," <i>Amer. J. path.</i> , 147: 155-165 (1995).					
	AS2	Holstein, A.F., <i>et al.</i> , "Different Epithelia in the Distal Human Male Urethra," <i>Cell Tiss. Res.</i> , 264: 23-32 (1991).					
	AT2	Durso, D.F., Introduction, pp. 1-1 to 1-3 in Davidson, R. L. editor, <i>Handbook of Water-Soluble Gums & Resins</i> , McGraw-Hill, Inc., N.Y. (1980).					
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AU2	Seaman, J.K., "Guar Gum," pp 6-1 to 6-19 in Davidson, R. L. editor, <i>Handbook of Water-Soluble Gums & Resins</i> , McGraw-Hill, Inc., N.Y. (1980).					
	AV2	Seaman, J.K., "Locust Bean Gum," pp 14-1 to 14-16 in Davidson, R. L. editor, <i>Handbook of Water-Soluble Gums & Resins</i> , McGraw-Hill, Inc., N.Y. (1980).					
	AW2	Williams C. <i>et al.</i> , "Efficacy and Safety of Transurethral Alprostadil Therapy in Men with Erectile Dysfunction," <i>Brit. J. Urol.</i> , 81: 889-894 (1998).					
	AX2	Physician's Desk Reference, 51 st Ed., pp. 2575-2576 (1997).					
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	AL5						
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AY2	<i>The Merck Index</i> , 12 th Ed., Merck & Co., N.J., pp. 1352-1354 (1996).					
	AZ2	<i>Martindale The Extra Pharmacopoeia</i> , 28 th Ed., London, The Pharmaceutical Press, p. 1353 (1982).					
	AR3	Kunelius, P., et al., "Intracavernous Self-injection of Prostaglandin E1 in the Treatment of Erectile Dysfunction," <i>International J. of Impot. Res.</i> , 11: 21-24 (1999).					
	AS3	Zecchi Orlandini, S., et al., "Ultrastructure of Human Male Urethra," <i>Archives of Andrology</i> , 23: 51-59 (1989).					
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	AA6						
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	AL6						
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AT3	Ishii, N., <i>et al.</i> , "Studies on Male Sexual Impotence Report II," <i>The Japanese J. of Urol.</i> , 77(9): 954-961 (1986).
AU3	Hedlund H., <i>et al.</i> , "Contraction and Relaxation Induced by some Porstanoids in Isolated Human Penile Erectile Tissue and Cavernous Artery," <i>J. of Urol.</i> , 154: 1245-1250 (1986).
AV3	Gerber, G.S., <i>et al.</i> , "Pharmacological Erection Program Using Prostaglandin E1," <i>J. of Urol.</i> , 146: 786-789 (1991).
AW3	Malloy, T.R., <i>et al.</i> , "Pharmacologic Treatment of Impotence," <i>Urologic Clinics of North America</i> , 14(2): 297-305.

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	AL7						
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	AO7						
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	AQ7						
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AX3	Wolfson, B., <i>et al.</i> , "Intralurethral Prostaglandin E-2 Cream: A Possible Alternative Treatment for Erectile Dysfunction," <i>Urology</i> , 42(1): 73-75.					
	AY3	Catanzarite, V.A., <i>et al.</i> , "Prostaglandins: Mundane and Visionary Applications," <i>Contemporary OB/GYN</i> , pp 21-41 (Oct 1987).					
	AZ3	Remington: Practice of the Science and Pharmacy, 19 th Edition Mack Publishing Company A.R. Gennaro (Ed.), pp. 410-412 (1995).					
	AR4	Chattaraj, S.C. and Walker, R.B., "Penetration Enhancer Classification" in <i>Percutaneous Penetration Enhancers</i> , E.W. Smith, H.I. Maibach (Eds.) CRC, Press, Inc. pp. 5-20 (1995).					
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	AL8						
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AS4	Büyüktimkin, <i>et al.</i> , "Alkyl N, N-Disubstituted-Amino Acetates" in <i>Percutaneous Penetration Enhancers</i> , E.W. Smith, H.I. Maibach (Eds.) CRC, Press, Inc., pp. 91-102 (1995).					
	AT4	Tiefer, L., <i>et al.</i> , <i>Impotence: NIH Consensus Statement</i> , 10(4): 1-31 (1993).					
	AU4	Sullivan, M.E. <i>et al.</i> , "Alterations in Endothelin B Receptor Sites in Cavemosal Tissue of Diabetic Rabbits: Potential Relevance to the Pathogenesis of Erectile Dysfunction," <i>J. Urol.</i> , 158 (5): 1966-72 (1997).					
	AV4	Sairam, K. <i>et al.</i> , "Prevalence of Undiagnosed Diabetes Mellitus in Male Erectile Dysfunction," <i>BJU Intl.</i> , 88(1): 68-71 (2001).					
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	AL9						
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AW4	Sullivan, M.E. <i>et al.</i> , "Nitric Oxide and Penile Erection: is Erectile Dysfunction Another Manifestation of Vascular Disease," <i>Cardiovasc. Res.</i> , 43(3): 658-65 (August 15, 1999).					
	AX4	DeAngelis, L., <i>et al.</i> , "Erectile and Endothelial Dysfunction in Type II Diabetes: a Possible Link," <i>Diabetologia</i> , 44(9): 1155-60 (2001).					
	AY4	Burchardt, T. <i>et al.</i> , "Reduction of Endothelial and Smooth Muscle Density in the Corpora Cavernosa of the Streptozotocin Induced Diabetic Rat," <i>J. Urol.</i> , 164(5): 1807-11 (2000).					
	AZ4	Hopfner, R.L. and Gopalakrishnan, V., "Endothelin: Emerging Role in Diabetic Vascular Complications," <i>Diabetologia</i> , 42(12): 1383-94 (1999).					
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	AL10						
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	AN10						
	AO10						
	AP10						
	AQ10						
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AR5	Sasayama, S. <i>et al.</i> , "Men's Health Study. Epidemiology of Erectile Dysfunction and Cardiovascular Disease," <i>Circ. J.</i> , 67: 656-659 (2000).					
	AS5	Zippe, C.D. <i>et al.</i> , "Management of Erectile Dysfunction Following Radical Prostatectomy," <i>Current Urology Reports</i> , 2: 495-503 (2001).					
	AT5	Catalona, W.J. <i>et al.</i> , "Nerve-sparing Radical Prostatectomy: Evaluation of Results after 250 Patients," <i>J. Urol.</i> , 143: 538-43 (1990).					
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			FILING DATE September 5, 2003		GROUP ART UNIT 1623		
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	AV5	Keogh, E.J., and Earle, C.M., "Intracavernosal Prostaglandin E1 and Penile Implant," <i>Int. J. Impotence Res.</i> , 4: 113 (1992).					
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	AR6	Padma-Nathan, H. "A New Era in the Treatment of Erectile Dysfunction," <i>American Journal of Cardiology</i> , 84(5B): 18N-23N (1999, September 9).					
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	AV6	Emilien, G., "Alprox-ID NexMed Inc.," <i>Current Opinion in Central and Peripheral Nervous System Investigational Drugs</i> , 2(3): 311-320 (2000).					
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